REMARKS

Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request reconsideration of the claims in view of the claim amendments and the remarks presented below. Claims 54-66 are pending in the application. No new matter is presented. Support for the claims can be found throughout the background of the invention, the specification and the drawings, and more particularly at page 3, line 28 to page 4, line 3; page 20, lines 15-30; page 27, lines 1-8; and page 27, line 25 to page 28, line 16.

Priority

The Examiner has requested that the priority data in the first line of the specification be updated. The Applicants have complied and amended the specification to update the status of all applications. No new matter has been added to the specification.

Information Disclosure Statement

The Examiner has indicated that the information disclosure statement filed February 2, 2005 fails to comply with 37 C.F.R. § 1.98(a)(1). The Applicants have revised the Information Disclosure Statement to comply with 37 C.F.R. § 1.98(a)(1) and are filing it as a Supplemental Information Disclosure Statement concurrently herewith.

Claim Rejections - 35 U.S.C. § 101

The Examiner has stated that "Claims 55, 61, and 63-66 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The language positively recites the combination of the human body and the cardiac harness and therefore is non-statutory because the human body is non-statutory. The Examiner recommends using "adapted to" language.

The Applicants have amended claims 55, 61, 63, and 65-66 using the "adapted to" language recommended by the Examiner. Claim 64 is dependent on claim 63 and should also now be in compliance with the request of the Examiner.

Claim Rejections - 35 USC § 112

The Examiner has stated that: "Claim 61 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The pressure range of 3 to 4 mmHg has not been previously set forth."

The Applicants respectfully traverse the rejection. In the specification at page 27, lines 1-2, "the compliance of the elastic harness 4 is in the range of compliance of native pericardium or latisimus dorsi muscle wraps." The Background of the Invention section of the specification, on page 3, lines 30-31 states: "Shabetai in The Role of the Pericardium in the Pathophysiology of Heart Failure notes that the pericardium exerts 3-4 mm Hg of pressure against the heart." Thus, the compliance of harness 4 is in the range of the native pericardium which is about 3-4 mm Hg pressure against the heart. Claim 61 is dependent on claim 60 which states in part: "apply pressure on the heart so that the compliance of the cardiac harness is in the range of compliance of the native pericardium." The pressure range of the native pericardium, as noted above, has been set forth in the Background of the Invention section of the specification. Therefore, the claim does comply with 35 U.S.C. 112, first paragraph. The Applicants respectfully ask that the Examiner withdraw the rejection.

Claim Rejections - 35 U.S.C. § 102(b)

The Examiner has stated that: "Claims 54-66 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cox et al. (5,150,706). Claim 54- net -12- is an elastic cardiac harness, column 5 lines 52 and 53. Net -12- would have a different compliance for different size hearts and different size elements. Therefore the examiner is taking the compliance as claimed as an inherent feature of Cox et al, when a certain size net -1 2- is

put on a certain size heart. Further, the compliance is directed to an intended use and method of using the device. If the claimed invention was on a shelf with net -12- of Cox et al. the devices could be identical."

The Examiner has further stated that: "Claims 54-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Alferness (5,702,343). Claim 54 - Alferness teaches a heart jacket formed of an elastic material, column 3 line 10. An elastic heart jacket, figures 3-5, is inherently self-sizing over the elastic range of the jacket."

The Applicants have amended claim 54 to state: A medical device to treat the heart, comprising: a cardiac harness that is self-sizing; the cardiac harness sized to cover at least a portion of the heart; and the cardiac harness being compressible to be implanted about the heart minimally invasively. Currently amended claim 54 is patentably distinct from Cox et al. Cox et al. does not disclose a cardiac harness that is capable of being applied about the heart minimally invasively. In fact, the net of Cox et al. is placed on a non-beating heart (see column 1, lines 11-34), therefore self-sizing and compliance are not factors that Cox et al. would be concerned with. The Cox et al. patent teaches a device that is to be applied upon a non-beating heart during open surgery, and removed before closing the skin incision. Cox et al., as shown in FIG. 3, discloses placement of the net during invasive surgery utilizing a rib retractor to keep the ribs distended, and further describes using sutures to keep open the walls of the pericardium. Cox et al. also describes a drawstring that must be tied in a knot. (Column 7, lines 21-30). Therefore, Cox et al. does not disclose a device that is capable of being implanted about the heart minimally invasively. Furthermore, because the Cox et al. device is not intended to be left in the patient after wound closure, Cox does not disclose a device that is "implanted." In addition, Cox does not disclose materials for manufacturing the net that are consistent with implantation about the heart.

The Applicants respectfully traverse the rejection of claim 54 as being anticipated by Alferness because claim 54 is patentably distinct from Alferness. Applicants request

that the Examiner reconsider the fact that Alferness does not disclose a device that is self-sizing. The Alferness device is a jacket and it is fundamentally different from the cardiac harness of the present invention. The Alferness jacket is just like the jacket you put on and zip closed. The Alferness jacket must be bigger than the heart on which it is mounted and then it is cinched down similar to a corset. Again, this procedure is done on a non-beating heart, so size is not as important to Alferness until the manual tighten step to cinch the jacket closed. Clearly, the Alferness jacket (corset) is not self-sizing when mounted on the heart. Alferness states that: "the expansion constraint applied to a heart by a CRD is predetermined by the physician." (Column 2, lines 66-67; column 3, lines 14-16; column 4, lines 1-11; column 4, lines 1-11). Alferness describes a device that is not self-sizing as the heart contracts, because the Alferness device is only an "expansion constraint." (Column 2, line 66-67). A self-sizing device is distinguishable because it is not a constraint at all, rather it is a restraint that automatically adjusts to reducing cardiac sizes as the heart contracts. Compare Alferness which states that the CRD is fitted to "a predetermined size" which is "adjusted for size reduction as the cardiac size is reduced." (Column 4, lines 9-11.) Alferness discloses a requirement to <u>manually</u> size the jacket as the heart size is reduced. Alferness teaches manually adjusting the sizing by "adjusting the proximity of the opposing lateral edges" (column 4, lines 57-59) (i.e., manually tightening the drawstrings on the corset) or by an inflatable member (column 4, lines 66-67). For all of the reasons stated above, Alferness does not disclose a cardiac harness that is self-sizing, and therefore claim 54 is patentably distinct.

Claim 54 is now in condition for allowance, and Applicant respectfully requests approval by the Examiner. Claims 55-59, which are dependent on claim 54 are also now in condition for allowance and Applicants respectfully request approval by the Examiner.

The Examiner has stated regarding Cox et al. and Alferness that: "Claims 60 and 61 - the net -12- would have pattern for applying a compressive force. The compliance is capable of being expressed in terms of the pressure the harness applies to the heart. The range of compliance is a function of the heart size and the size of the jacket. The selection

of a particular jacket for use on a particular heart would provide the claimed compliance. Therefore the jacket is capable of providing the claimed compliance."

Applicants respectfully traverse the rejection. Applicants respectfully request that the Examiner reconsider the rejection because claim 60 can be distinguished from both Cox et al. and Alferness. Claim 60 recites a cardiac harness configured "to apply pressure on the heart so that the compliance of the cardiac harness is in the range of compliance of the native pericardium." Neither Cox et al. nor Alferness disclose a compliance of their devices that is in the range of compliance of the native pericardium. In the specification at page 27, lines 1-2 "the compliance of the elastic harness 4 is in the range of compliance of native pericardium or latisimus dorsi muscle wraps." The Background of the Invention section of the present specification, on page 3, lines 30-31 states: "Shabetai in The Role of the Pericardium in the Pathophysiology of Heart Failure notes that the pericardium exerts 3-4 mm Hg of pressure against the heart." Cox et al. does not disclose a net that maintains pressures within the claimed range. Likewise, Alferness does not disclose a jacket that maintains pressures within the claimed range.

Furthermore, the Applicant respectfully requests that the Examiner reconsider Examiner's statement that: "The range of compliance is a function of the heart size and the size of the jacket." The range of compliance of a cardiac jacket is in fact more than a function of just the heart size and the size of the jacket, just as the range of compliance of the native pericardium is more than a function of just the heart size and the size of the pericardium. The tissue makeup of the human pericardium is responsible in a large part for the pressure-volume responses of the pericardium over the cardiac cycle. Likewise, the structural configuration of a harness, the pattern of the harness, and the materials making up the harness will all have an effect on the compliance of the device. Cox et al. and Alferness do not disclose or teach how to make a harness that performs like the human pericardium and that maintains pressure on the heart so that the compliance of the cardiac harness is in the range of compliance of the native pericardium.

The Applicants therefore respectfully request that the Examiner find claim 60 is in condition for allowance, and Applicants respectfully request approval by the Examiner. Further, the Applicants request that the Examiner find claims 61-66, which are dependent on claim 60, are also now in condition for allowance. Applicants respectfully request approval by the Examiner for issuance of these claims.

Double Patenting

The Examiner has stated that: "Claims 54-60 and 62-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 18 of U.S. Patent No. 6,723,041; Claims 54-60 and 62-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of U.S. Patent No. 6,702,732; Claims 54-60 and 62-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,682,474; Claims 54-60 and 62-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,663,558; and Claims 54-60 and 62-64 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,595,912."

Applicants assert that U.S. Patent No. 6,723,041; U.S. Patent No. 6,702,732; U.S. Patent No. 6,682,474; U.S. Patent No. 6,663,558; and U.S. Patent No. 6,595,912 have common ownership with the present application. Applicants have included with this response a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) to overcome the double patenting rejection of the Examiner.

Applicants respectfully request that the Examiner find all claims in condition for allowance. The Applicants respectfully request approval by the Examiner.

Respectfully submitted,

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